

INDWELLING DEVICE

FIELD OF THE INVENTION

The present invention is in the field of medical devices, and more specifically relates to indwelling medical devices.

BACKGROUND OF THE INVENTION

5 There are many medical devices that are inserted into the body and left indwelling for a prolonged period of time. These include, for example, various types of catheters, cannulae, drains, implants, stents, pacemakers, electrodes and other devices. Some of these devices, such as a urinary catheter, when in use, extend from the exterior of the body into the body interior, passing through an
10 orifice on the body surface. The orifice may be a natural orifice (e.g. mouth, meatus, nostrils, etc.) or an artificial orifice (e.g. a hole formed in the skin by a surgical incision). Other indwelling devices, such as a pacemaker or stent, are completely enclosed inside the body during use. Accessing these devices typically requires surgical incising or other invasive approaches.

15 Although using indwelling devices is a common medical procedure, it is often limited due to formation of biofilm such as calcifications and other debris, and colonization of microorganisms, such as bacteria and fungi, on the surface on the device. This may cause inflammation and further infection around the device. The formation of biofilm and contamination is common with exposed indwelling
20 devices, limiting the amount of time that they may be left in the body before having to be removed and possibly replaced with a new device.

Contamination of the device and tissues surrounding it may occur as the device is inserted into the body. For example, the end of a urethra closest to the

meatus is naturally contaminated with various infectious agents, while the remainder of the urethra, nearer to the urinary bladder is normally sterile. During insertion of a catheter through the urethra to the urinary bladder, the catheter contacts infectious agents in the beginning of the urethra and spreads them up the urethra into the normally sterile portion and into the bladder. In order to reduce the spread of microorganisms up the urethra during insertion of a urinary catheter, it is known to first insert a hollow sheath into the beginning of the urethra that extends in the urethra to just beyond the contaminated region. A urinary catheter is then inserted through the sheath into the normally sterile part of the urethra, and into the bladder. The sheath thus intervenes between the catheter and the microorganisms in the infected part of the urethra, and thus decreases the chance of microorganisms spreading into the normally sterile portion of the urethra and into the bladder. After insertion of the catheter, the sheath is withdrawn from the body. Such sheaths are disclosed, for example, in U.S. Patent No. 5,417,666.

Microorganisms may also migrate along an exposed indwelling device after its insertion along the outside surface of the device at its interface with the surrounding tissue. In order to inhibit the migration of microorganisms along the device, it is known to impregnate the device with antiseptic substances that are released from the catheter over time. A catheter designed to release antiseptic substances is disclosed, for example, in U.S. Patent No. 3,598,127. Antiseptic impregnation, however, is not effective in the prevention of biofilm formation and is of very limited value in preventing infection due to the development of resistance among the microorganisms to the antibiotic.

SUMMARY OF THE INVENTION

The present invention provides indwelling medical devices having an outer surface at least a portion of which is protected by a manually detachable cover. During insertion, the cover is attached to the surface so as to prevent relative movement of the surface and the cover. This allows the integrity of the device and cover to be maintained during insertion. At any time after insertion, the cover may

be detached from the shaft and removed from the body, leaving the device in place. Removing the cover from the device removes the biofilm and contamination that has accumulated on the cover.

The cover is preferably made from non-allergic biocompatible materials such as silicone rubber, latex, woven metal mesh, parylene, polyvinylchloride, and the like. The cover may be impermeable to body fluids or microorganisms. The cover may have a rough or smooth surface.

In a preferred embodiment, the device has a surface that is protected by a stack of two or more sequentially detachable covers. A first, innermost, cover is in direct contact with the surface. A second detachable cover is in contact with the first cover, so that the first cover is between the second cover and the surface. Additional covers may also be present, as required. At any time after insertion of the device into the body, the outermost cover may be detached from the surface and removed from the body, leaving the device in place with one less cover over the surface. The newly exposed outermost cover may, later on, be detached from the surface and removed from the body. This process may be repeated until all of the covers have been removed. When using multiple covers, the covers may be made from the same material as the surface of the device or from a different material. the covers may be identical or different. They may be made from different materials or the same material. The thickness of each layer may be the same or different.

A detachable cover for a device may be made using a pre-formed cover that is applied to the surface. A cover may be formed having a lumen that is dimensioned to receive the entire device, or a portion of it in the lumen. Alternatively, a liquid coating substance may be applied to the device or to a portion of its surface and allowed to solidify by curing, polymerizing, or drying. For example, a 2:1 solution of silicone rubber:toluene may be applied to the surface and allowed to dry and cure. The coating substance may be applied to the device or an outermost detachable cover previously applied to the surface, for example, by brushing, immersion, spraying, or any other method of deposition.

Two adjacent members (a detachable outermost cover and the surface of the device, or two adjacent detachable covers on a multiple coated device), may be

reversibly attached to each other by any known method. For example, an adhesive may be introduced between the members and allowed to cure. The bond formed by the adhesive is subsequently broken when desired, for example, by applying an axial or radially outward force to the outermost member so as to break the bond.

5 Alternatively, the bond may be broken by introducing a fluid between the members that breaks the bond either chemically or mechanically. As yet another alternative, the bond may be broken over time, either spontaneously or during prolonged contact of the adhesive with body fluids such as blood plasma or urine.

The reversible attachment of the two adjacent members may extend along
10 the entire contact area between the members, or only at specific regions between the members. For example, one or more clips may be disposed on the device that presses the outermost cover to the underlying member at various locations. The clips may be formed, for example, by a rubber ring that may be rolled onto the outermost layer. The outermost layer is detached by cutting the ring or by rolling it
15 off the outermost layer. The clip may be a toroidal balloon that constricts the members when inflated and releases the attachment when deflated.

A detachable cover may be made from an elastic material. An elastic cylinder may be stretched over the shaft of a catheter or over detachable covers already present on the shaft and allowed to contract with the shaft and any
20 previously existing detachable covers in its lumen. In this case, a reversible attachment is formed between the new cover and an adjacent member by the elastic forces of the new outermost cover. The attachment may be broken by making a longitudinal cut along the outermost cover. The cover may have one or more lines of preformed perforations that are easily torn by splaying apart an end of the
25 coating.

The space between the device and a cover or between two adjacent covers may contain material to reinforce the attachment or to enhance relative sliding. The material may repel deposits or have anti-microbial properties. The interface material can be the same or different, for each pair of adjacent members. For
30 example, mineral oil may be present to enhance sliding and prevent penetration of contamination between the members.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, preferred embodiments will now be described, by way of non-limiting examples only, with reference to the accompanying drawings, in which:

5 Fig. 1 shows an indwelling device having a tearable cover in accordance with one embodiment of the invention;

 Fig. 2 shows an indwelling device having a cutable cover in accordance with another embodiment of the invention;

10 Fig. 3 shows an indwelling device having a rollable cover in accordance with another embodiment of the invention;

 Fig. 4 shows an indwelling device having a helical cover in accordance with another embodiment of the invention;

 Fig. 5 shows an indwelling device having a cover attached with internal balloons in accordance with another embodiment of the invention;

15 Fig. 6 shows use of a clamp securing the distal end of a cover to a surface.

 Fig. 7 shows an indwelling device having a cover attached on an inner surface;

 Fig. 8 shows an indwelling device having a tearable cover in accordance with another embodiment of the invention.

20 Fig. 9 shows a system for preparing a cover on a mandrill in accordance with one embodiment of the invention; and

 Fig. 10 shows a system for transferring a cover from a mandrill onto a device.

25 DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

The invention will now be described by non-limiting embodiments. For the sake of clarity, the invention is exemplified by devices having a slender shaft such as catheters, cannulae, and drains. This is by way of example only, however, and the invention is not limited to such devices. Other devices having detachable

covers are included within the scope of the invention, such as implants, stents, and pacemakers.

5 **First Embodiment**

Fig. 1a shows an indwelling device 100 in accordance with a first embodiment of the invention. The device 100 has a proximal end 102, a distal end 104, and a cylindrical shaft 105 that may be solid or hollow. The shaft 105 is contained in an outer cover 110 having the general shape of a thin cylindrical shell.

10 The outer cover 110 is formed from a biocompatible, elastic material, such as latex, that was stretched over the shaft 105, and allowed to contract on the shaft 105. The outer cover 110 is reversibly attached to the shaft 105 by circumferential elastic forces in the outer cover 110 that are exerted on the shaft 105. This prevents slipping of the outer cover 110 over the shaft 105 during insertion of the device 100

15 into the body, and maintains the outer cover 110 on the shaft 105 after insertion.

The outer cover 110 is formed from two materials. The first material is used to form the cover except in a narrow strip 125 that is formed from a second material. The two materials are joined at two parallel seams 120a and 120b extending along the length of the outer cover 110. The strip of 125 formed from the

20 second material preferably extends circumferentially for less than one quarter of the circumference of the outer cover 110. The first material has a relatively high tear stress, for example, a silicone rubber having a tear stress of 25 to 50 kN/M. the second material has a relatively low tear stress, such as a silicone rubber having a tear stress of less than 5 kN/M. The preparation of silicone rubbers and other

25 materials having a particular tear stress are known in the art.

Between the shaft 105 and the outer cover 110 is a cord 130. The cord is attached at one of its ends to the distal end of the strip 125. At its other end, the cord extends beyond the proximal end of the coating. A ring 150 holds the end of cord 130 on the shaft 105. As shown in Fig. 6, the device 100 may optionally

30 comprise a distally located annular clamp 610 that secures the distal end of the

outer cover 110 to the shaft 105 and prevents debris from accumulating under the distal end of the outer cover 110 during insertion.

Fig. 1b shows the catheter of Fig. 1a after insertion into the body. The catheter 100 was inserted into the body through a hole 135 on the body surface 140.

5 The hole 135 may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the cord 130 extends through the hole 135 and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical
10 cut is made in order to access the proximal end of the cord 130. Relative movement of the shaft 105 and the outer cover 110 is prevented during insertion due to the circumferential elastic forces of the outer cover 110 on the shaft 105.

At any time after insertion, the outer cover 110 may be detached from the device 100 by removing the ring 150 and pulling the distal end of the cord 130.
15 Pulling the cord 130 away from the body draws the distal end of the strip 125 into the space between the coating 110 and the shaft 105, tearing the distal ends of the seams 120a and 120b. (Fig. 1c). As the cord 130 continues to be pulled, tearing of the seams 120a and 120b progresses from the distal end towards the proximal end, until the entire strip 125 has been detached from the rest of the layer 110 and
20 removed from the body (Fig. 1d). This detaches the outer cover 110 to the shaft 105. The proximal end of the torn outer cover 110 may now be grasped and manually removed from the body leaving the device 100 in place. If after removal of the outer cover 110, a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the
25 device.

Fig. 9 shows a system, generally indicated by 900 for preparing the cover 110. A reservoir 905 contains a first liquid suspension 910 for preparing the first material in the cover 110. A cylindrical mandrill 915 is used upon which the cover 110 is to be formed. The mandrill 915 has a diameter corresponding to the inner
30 diameter of the cover 110. A length of the mandrill 915 is submerged in the

suspension 910. As the mandrill 915 is withdrawn from the suspension 910, a layer 920 of the first material coating the mandrill is formed.

A wiper blade 925 is used to remove a portion of the coating 920 as the mandrill 915 is withdrawn from the suspension 910. Above the wiper 925, a narrow strip 930 of the surface of the mandrill 915 thus becomes exposed.

A second reservoir 935 contains a second suspension 940 that is used to form the second material of the coating 110. The second suspension 940 is delivered to the surface of the mandrill 915 through a tube 945. A nozzle 950 applies the second suspension to the exposed strip 930 of the mandrill 915 surface, as the mandrill 915 is withdrawn from the first suspension 910. The second suspension 940 thus forms a coating 955 on the mandrill 915 in the exposed strip 930 created by the wiper 925.

Fig. 9c shows the mandrill 915 after having been removed from the reservoir 905. A cylindrical coating 960 has been formed on the mandrill 915. The coating consists of the first portion 920 formed by the first suspension 910 and the second portion 955 formed by the second suspension 940. The mandrill 915 is then placed in an oven in order to allow the coating to cure so as to form the cover 110. The first suspension 910 thus formed the first material of the cover, and the second suspension 940 formed the second material.

Fig. 10 shows a system, generally indicated by 1000, for transferring the cover 110 from the mandrill 915 to the shaft 105 of the device 100. The system 1000 is shown in plan view in Fig. 10a and in cross-section in Fig. 10b. The system 1000 has a housing 1005. A cylindrical tube 1010 passes through the housing 1005 and has a diameter configured to alternately receive the coated mandrill 915 and the shaft 105 of the device 100, as described below.

Fig. 10b shows the interior 1015 of the system 1000. A cylindrical space 1020 surrounds the cylinder 1010. The wall 1022 that is common to the space 1020 and the cylinder 1010 contains a plurality of pores 1025 allowing the flow of air between the interior 1015 of the cylinder 1010 and the space 1020. When the ends of the cylinder 1010 are sealed, as described below, the chambers 1015 and 1020

may be evacuated by removing air in the chambers through a tube 1027 that is connected to a source of negative pressure (not shown).

Fig. 10c shows the system 1000 after the mandrill 915 has been inserted into the cylindrical tube 1010. As described above, the mandrill 915 is contained in the cover 110 that is to be transferred from the mandrill 915 to the shaft 105 of the device 100.

As shown in Fig. 10d, the ends 128 of the cover 110 are then rolled off the mandrill 915 and onto the ends of the tube 1010, thus sealing the ends of the cylinder 1010. The chamber 1020 is then evacuated causing the cover 110 to dissociate from the mandrill 915 and associated with the to the inner surface of the cylinder 1010, as shown in Fig. 10e. Dissociation of the cover 110 from the mandrill 915 may be enhanced if the mandrill is formed with a hollow core 1030 that is confluent with the exterior by pores 1035 in the wall of the mandrill 915, as shown in Fig. 10f. A source of positive pressure (not shown) is applied to the core 1030 by means of a tube 1040. The mandrill is then removed from the cylinder 1010 leaving the cover 110 mounted on the inner surface of the cylinder 1010, as shown in Fig. 10f.

Now the shaft 105 of the device 100 is inserted into the cylinder 1010 as shown in Fig. 10 g. . The source of negative pressure is then disconnected from the tube 1027, causing the cover 110 to dissociate from the wall of the cylinder 1010 and associate with the shaft 105 of the device 100, as shown in Fig. 10h. The ends of the cover 110 are then unrolled from the cylinder 1010 onto the shaft 105, and the shaft 105 is removed from the interior of the cylinder 1010 with the cover 110 in place.

Second Embodiment

Fig. 2a shows an indwelling device 200 in accordance with another embodiment of the invention. The device 200 has a proximal end 202, a distal end 204, and a cylindrical shaft 205 that may be solid or hollow. The shaft 205 is contained in an outer cover 210 having the general shape of a thin cylindrical shell. The outer cover 210 is formed from a biocompatible, elastic material, such as latex,

that was stretched over the shaft 205, and allowed to contract on the shaft 205. The outer cover 210 is reversibly attached to the shaft 205 by circumferential elastic forces in the outer cover 210 that are exerted on the shaft 205. This prevents slipping of the outer cover 210 over the shaft 205 during insertion of the device 200 into the body, and maintains the outer cover 210 on the shaft 205 after insertion.

As shown in the insert Fig. 2a-I of Fig. 2a, the shaft has a longitudinal groove 215 that forms a track for a blade 220. The blade 220 is slidable along the groove 215. During insertion into the body, the blade 220 is positioned at the distal end of the groove 215. Between the shaft 205 and the outer cover 210 is a cord 230. The cord is attached at one of its ends to the blade 220. At its other end, the cord 215 extends beyond the proximal end of the coating.

Fig. 2b shows the device 200 after insertion into the body. The device 200 was inserted into the body through a hole 235 on the body surface 240. The hole 235 may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the cord 230 extends through the hole 235 and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the cord 230. Relative movement of the shaft 205 and the outer cover 210 is prevented during insertion due to the circumferential elastic forces of the outer cover 210 on the shaft 205.

At any time after insertion, the outer cover 210 may be detached from the device 200 by pulling the proximal end of the cord 230. Pulling the cord 230 away from the body draws the blade 220 towards the proximal end of the shaft 205 thus making a longitudinal cut 233 in the cover 210. (Fig. 2c). A guard 222 (Fig. 2a-I) on the blade prevents the blade from cutting any underlying covers. As the cord 230 continues to be pulled, cutting of the cover 210 progresses from the distal end towards the proximal end, until the cut extends along the entire length of the cover 210. This detaches the outer cover 210 from the shaft 205. The proximal end of the cut outer cover 210 may now be grasped and manually removed from the body

leaving the device 200 in place. If after removal of the outer cover 210, a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

5 **Third Embodiment**

Fig. 3a shows a device 300 in accordance with an other embodiment of the invention. The device 300 has a proximal end 302, a distal end 304, and a cylindrical shaft 305. The shaft 305 is contained in an outer cover 310 having the general shape of a thin cylindrical shell. The outer cover 310 is formed from a biocompatible, elastic material, such as latex. The outer cover 310 was formed from an inner cylindrical shell 322 and an outer cylindrical shell 324. The inner and outer shells 322 and 324 are welded together at a first circular seam 326 at its distal end and a second circular seam 327 at its proximal end. The outer cover 310 was stretched over the shaft 305, and allowed to constrict on the shaft 305. The outer cover 310 is reversibly attached to the shaft 305 by circumferential elastic forces in the outer cover 310 that are exerted on the shaft 305. This prevents movement of the outer cover 310 relative to the shaft 305 during insertion of the device 300 and maintains the outer cover 310 on the shaft 305 after insertion.

Fig. 3b shows the device of Fig. 3a after insertion into the body. The catheter 300 was inserted into the body through a hole 335 on the body surface 340. The hole 335 may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). The proximal end of the outer cover 310 extends through the hole 335 and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the outer cover 310. Relative movement of the shaft 305 and the outer cover 310 is prevented during insertion due to the circumferential elastic forces of the outer cover 310 on the shaft 305.

At any time after insertion, the outer cover 310 may be detached from the device 300 by causing the outer cylindrical shell 324 to slide proximally over the

inner cylindrical shell 322. As shown in Fig. 3c, this may be accomplished by placing a thumb 330 and an index finger 332 on the outer cylindrical shell 324 and urging the outer cylindrical shell 324 to slide proximally over the inner cylindrical shell 322, as indicated by the arrow 342. This draws the distal end of the inner cylindrical shell 322 into the outer shell 324, while the remainder of the inner shell remains stationary, relative to the shaft 305. As the outer shell 324 continues to slide proximally, the shaft 305 becomes progressively more exposed at its distal end, as shown in Fig. 3d. This process continues until the shaft 305 has been completely exposed and the outer cover 310 has been removed from the body. If after removal of the outer cover 310, a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Fourth Embodiment

Fig. 4a shows an indwelling device 400 in accordance with another embodiment of the invention. The device 400 has a proximal end 402, a distal end 404, and a cylindrical shaft 405 that may be solid or hollow. The shaft 405 is contained in an outer cover 410 having the general shape of a thin cylindrical shell. The outer cover 410 is formed from a strip of biocompatible material, such as latex or silicone rubber. The outer cover 410 is formed by winding the strip of biocompatible material in a helical pattern around the length of the shaft 405. Consecutive turns of the helix overlap so as to completely cover the shaft 405. The distal end 411 of the strip is tucked under the first few turns of the helix, so as to immobilize the distal end of the strip as shown in the insert to Fig. 4a. The proximal end of the strip is held in place by a ring 425. The ring 425 has a lumen dimensioned to fit snugly on the shaft 405 and the proximal end of the outer cover 410. This prevents slipping of the outer cover 410 over the shaft 405 during insertion of the device 400 into the body, and maintains the outer cover 410 on the shaft 405 after insertion.

Fig. 4b shows the device of Fig. 4a after insertion into the body. The device 400 was inserted into the body through a hole 435 on the body surface 440. The hole 435 may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the device 400, including the ring 425, extends through the hole 435 and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the device 400 and the ring 425. Relative movement of the shaft 405 and the outer cover 410 is prevented during insertion due to the radial force of the ring 425 on the proximal end of the outer cover 410, and the radial force of the last few turns of the helix on the distal end of the outer cover 410.

At any time after insertion, the outer cover 410 may be detached from the device 400. Referring to Fig. 4c, the ring 425 is removed from the shaft 405 and the outer cover 410 is unwound from its proximal end 408. (Fig. 4c). The outer cover 410 continues to be unwound, until the distal end of the outer cover 410 is freed. The proximal end of the outer cover 410 may now be grasped and manually removed from the body leaving the device 400 in place. If after removal of the outer cover 410, a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Fifth embodiment

Fig. 5a shows an indwelling device 500 in accordance with another embodiment of the invention. The device 500 has a proximal end 502, a distal end 504, and a cylindrical shaft 505 that may be solid or hollow. The shaft 505 is contained in an outer cover 510 having the general shape of a thin cylindrical shell. The outer cover 510 is formed from a biocompatible, rigid material, such as plastic or metal. On or more balloons 515 are located in a space 520 formed between the outer cover 510 and the shaft 505. In Fig. 5a, the balloons are shown in their deflated state. As shown in Fig. 5b, before inserting the device 500 into the body,

the balloons 515 are inflated with a fluid such as air or water. A syringe 525 containing the fluid 530 is inserted into a valve 570.

The balloons are inflated by opening the valve 570 and depressing the plunger 550 of the syringe. The fluid 530 is conducted from the syringe 525 through a first tube 560 and then through a second tube 565 running along the shaft 505 and then into each of the balloons 515. When inflated, the balloons apply a pressure to both the shaft 515 and the outer cover 510. The valve 540 is then closed to prevent fluid from leaving the balloons. The outer cover 510 thus becomes reversibly attached to the shaft 505 by the balloons 515 that are lodged between the outer cover 510 and the shaft 505.

Fig. 5c shows the device of Fig. 5a and b after insertion into the body. The device 500 was inserted into the body through a hole 535 on the body surface 540. The hole 535 may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the device extends through the hole 535 and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the cover 510.

At any time after insertion, the outer cover 510 may be detached from the device 100 by deflating the balloons 515. This may be done, for example, by inserting the syringe 530 into the valve 570 and drawing the fluid from the balloons so as to puncture the balloon by pulling on the plunger 550. Once the balloons have been deflated, the proximal end of the device 500 may be grasped and manually removed from the body leaving the device 500 in place. If after removal of the outer cover 510, a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Sixth Embodiment

Fig. 7 shows an indwelling device 700 in accordance with another embodiment of the invention. The device 700 has a proximal end 702, a distal end 704, and a hollow cylindrical shaft 705. The shaft 705 has a lumen 708. In this embodiment, the cover 710 lines the inner surface of the hollow shaft 705. The lumen 708 contains a cover 710 having the general shape of a thin cylindrical shell covering the wall of the lumen 708. The cover 710 is formed from a biocompatible, rigid material, such as plastic. The proximal end of the cover 710 is glued to the lumen of a restraining ring 711. A circumferential clamp 750 around the ring 711 secures the ring 711 to the proximal end 702 of the device 700.

Fig. 7b shows the catheter of Fig. 7a after insertion into the body. The catheter 700 was inserted into the body through a hole 735 on the body surface 740. The hole 735 may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the device extends through the hole 735 and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the device 700.

Fig. 7b further shows removal of the outer cover. The ring 711 is detached from the proximal end 702 of the device 700, and the ring 711 is removed from the device 700 together with the cover 710 attached to it. As the ring 711 continues to be pulled away from the proximal end 702 of the device 700, the cover 710 becomes attenuated and detaches from the inner surface of the shaft lumen 708. If after removal of the outer cover 710, a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Seventh embodiment

Fig. 8a shows an indwelling device 800 in accordance with a first embodiment of the invention. The device 800 has a proximal end 802, a distal end 804, and a cylindrical shaft 805 that may be solid or hollow. The shaft 805 is

contained in an outer cover 810 having the general shape of a thin cylindrical shell. The outer cover 810 is formed from a biocompatible, elastic material, such as latex, that was stretched over the shaft 805, and allowed to contract on the shaft 805. The outer cover 810 is reversibly attached to the shaft 805 by circumferential elastic forces in the outer cover 810 that are exerted on the shaft 805. This prevents slipping of the outer cover 810 over the shaft 805 during insertion of the device 800 into the body, and maintains the outer cover 810 on the shaft 805 after insertion.

The outer cover 810 has a line of perforation 820 extending along the length of the outer cover 810. A ring 811 located on the shaft 805 contains a cord 830 that fixes the proximal end of the cover 810 onto the shaft 805. As shown in Fig. 6, the device 800 may optionally comprise a distally located annular clamp 615 that secures the distal end of the outer cover 810 to the shaft 805 and prevents debris from accumulating under the distal end of the outer cover 810 during insertion.

Fig. 8b shows the device 800 after insertion into the body. The device 800 was inserted into the body through a hole 835 on the body surface 840. The hole 835 may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the device 800 extends through the hole 835 and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the cord 830. Relative movement of the shaft 805 and the outer cover 810 is prevented during insertion due to the circumferential elastic forces of the outer cover 810 on the shaft 805.

At any time after insertion, the outer cover 810 may be detached from the device 800. The cord 830 is released as shown in Fig. 8c. The proximal end of the perforation 820 is then torn. The cover 810 is then made to slide proximally over the shaft 805 as shown in Fig. 8d. This causes a new region of the perforation 820 to be exposed outside the body. This section of the perforation is then torn, and the cover 810 is then made to slide proximally over the shaft 805 (Fig. 8d). This process continues until all of the perforation 820 is completely torn, and the cover

is removed from the body. If after removal of the outer cover 810, a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

204720-244401